UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as the Secretary of the United States Department of Health and Human Services,

Defendant.

No. 2:21-cv-00326-SMJ

ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION

Before the Court, without oral argument, is Plaintiff's Motion for Preliminary Injunction, ECF No. 6. The Court has reviewed the record and pleadings in this matter, is fully informed, and denies the motion.

BACKGROUND

The Court has previously set forth the facts relevant to this dispute in several orders issued in a related case: *Olsen v. Azar*, No. 20-cv-00374-SMJ (E.D. Wash) ("*Olsen I*"), ECF Nos. 34, 39, 50. Briefly, though, Plaintiff Jeremy Olsen is a Type I diabetic who has suffered kidney failure and undergone a kidney transplant due to his condition. *Olsen I,* ECF No. 1 at 10. Plaintiff uses a Medtronic MiniMed Continuous Glucose Monitor ("CGM"), which he alleges a doctor prescribed to

help avoid failure of his transplanted kidney and prevent other complications from his diabetes. *Id.* at 11. After his claim for Medicare coverage of the CGM supplies was initially denied as not "durable medical equipment," an Administrative Law Judge eventually approved Plaintiff's claim. *Id.* at 11–12. But the Medicare Appeals Council/Departmental Review Board ("Appeals Council") reversed the ALJ, determining that a CGM is not "durable medical equipment" because it is not "primarily and customarily used to serve a medical purpose." *Id.* at 12.

On December 23, 2019, Plaintiff sought judicial review,[1] alleging six causes of action. *See generally id.* Relevant here, Plaintiff claimed the Appeals Council based its decision on CMS-1682-R, a "final opinion and order" regarding CGM coverage, which the Department of Health and Human Services issued without a public notice and comment period. *Id.* at 8. He also argued substantial evidence did not support the Appeals Council's decision to deny coverage and its decision was arbitrary and capricious. *Id.* at 15. The Court granted Plaintiff's motion for summary judgment and ordered Defendant to provide coverage, finding that Plaintiff's CGM constitutes durable medical equipment. *Olsen I*, ECF No. 39. The Court also granted Plaintiff's motion for attorney fees, finding that Defendant's position in defending this matter was in bad faith. *Olsen I*, ECF No. 50.

[1] Plaintiff filed the lawsuit in the U.S. District Court for the District of Columbia, but the case was transferred to this Court. *Olsen I*, ECF No. 16.

Thereafter, Defendant again denied two of Plaintiff's claims for coverage of CGM supplies submitted during the pendency of *Olsen I*. Both claims were for reimbursement of a 90-day supply of CGM sensors that Plaintiff's supplier, MiniMed Distribution Corporation ("MiniMed") furnished to Plaintiff on April 19, 2019 (the "April 2019 claim") and March 10, 2021 (the "March 2021 claim"). Defendant admits the claims were erroneously denied but attributes the denials to a Medicare Administrative Contractor ("MAC") employee's failure "to make a manual adjustment to the submission code assigned to Plaintiff's claims in the contractor's claims processing system that was needed to facilitate payment." ECF No. 18 at 3.

Defendant requested ALJ hearings to challenge both denials. The April 2019 claim was rejected by the Appeals Council on October 22, 2021, ECF No. 32-1 at 3, and the March 2021 claim was denied by an ALJ on October 30, 2021, ECF No. 32-2 at 67.[2] In denying the claims, both the Appeals Council and ALJ relied on CMS-1682-R to conclude that CGM does not constitute durable medical equipment, in direct contravention of this Court's previous order. ECF Nos. 32-1 at 8; 32-2 at 71; *see also Olsen I* at ECF No. 39 ("[T]he Court joins the district courts who have found that the CGM constitutes durable medical equipment.").

[2] Following the ALJ's unfavorable decision on the March 2021 claim, the Appeals Council subsequently denied Plaintiff's request for expedited access to judicial review pursuant to 42 C.F.R. § 405.990. ECF No. 1 at 18.

Nonetheless, neither party disputes that the claims were eventually paid on July 15, 2021, along with other claims for CGM sensors submitted by Plaintiff.[3] ECF No. 16 at 15. Plaintiff now requests a nationwide preliminary injunction "barring the Secretary from continuing to reject continuous glucose monitor (CGM) claims based on CMS 1682-R and/or the claim that a CGM is not 'primarily and customarily used to serve a medical purpose.'" ECF No. 6 at 2. As Defendant notes, this request goes beyond Plaintiff's own claims at issue here and would apply to current or future claims by unidentified non-parties. ECF No. 18 at 4. Defendant opposes the motion, arguing that Plaintiff's claim is moot, and alternatively that Plaintiff cannot show he is entitled to preliminary injunction under the applicable standard. *See generally* ECF No. 18.

LEGAL STANDARD

A. Mootness

"Article III, § 2, of the Constitution limits the jurisdiction of federal courts to 'Cases" and "Controversies,' which restricts the authority of federal courts to resolving 'the legal rights of litigants in actual controversies.'" *Genesis Healthcare Corp. v. Symczyk*, 569 U.S. 66, 71 (2013) (cleaned up). "A moot case presents no

[3] Defendant represents that "[t]he MAC and its employees have been re-educated to ensure that the required manual adjustment is made going forward." ECF No. 16 at 3.

Article III case or controversy, and a court has no constitutional jurisdiction to resolve the issues it presents." *Goldin v. Bartholow*, 166 F.3d 710, 717 (5th Cir.1999); *see also Oregon v. FERC*, 636 F.3d 1203, 1206 (9th Cir. 2011) ("A case is moot when it has lost its character as a present, live controversy of the kind that must exist if we are to avoid advisory opinions on abstract propositions of law.") (internal quotation marks omitted).

A claim "becomes moot when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Murphy v. Hunt*, 455 U.S. 478, 481 (1982) (cleaned up). In general, an issue is no longer live when a party's injury is not redressable by a favorable decision. *Id.*; *see also Lee v. Schmidt-Wenzel*, 766 F.2d 1387, 1389 (9th Cir. 1985) ("[A] live question is no longer present because even a favorable decision by the district court would not have entitled the appellees to relief.").).

Under the "voluntary cessation" exception to mootness, it is well established that the "voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice." *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000). Rather, a party's voluntary abandonment of a challenged practice will moot a case only when "it can be said with assurance that there is no reasonable expectation that the alleged violation will recur and interim relief or events have completely and

irrevocably eradicated the effects of the alleged violation." *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Vilsack*, 6 F.4th 983, 991 (9th Cir. 2021). In analyzing voluntary cessation, "[t]he government receives greater deference than private parties." *Id.* However, the government "must still demonstrate that the change in its behavior is entrenched or permanent." *Id.* (quoting *Fikre v. Fed. Bureau of Investigation*, 904 F.3d 1033, 1037 (9th Cir. 2018)). In other words, the court must be assured that "the challenged conduct cannot reasonably be expected to start up again." *Fikre*, 904 F.3d at 1037.

B. Preliminary Injunction

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To prevail on a request for a preliminary injunction, a plaintiff "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* at 20. In assessing whether a plaintiff is entitled to a preliminary injunction, "courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982).

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DISCUSSION

Plaintiff argues that he is entitled to a preliminary injunction "barring the Secretary from continuing to reject continuous glucose monitor (CGM) claims based on CMS 1682-R and/or the claim that a CGM is not 'primarily and customarily used to serve a medical purpose.'" ECF No. 6 at 1. The Court interprets this request as a request for a nationwide preliminary injunction. Defendant opposes the motion on jurisdictional grounds and on the merits.

A. Plaintiff's claim for injunctive relief is not moot.

As a threshold matter, the Court finds that Plaintiff's claim for injunctive relief is not moot. While it undisputed that each claim for reimbursement has in fact been paid, the Government has not met its "heavy burden of persua[ding]" the Court under the voluntary cessation doctrine. *United States v. Concentrated Phosphate Exp. Ass'n*, 393 U.S. 199, 203 (1968). "[A] voluntary change in official stance or behavior moots an action only when it is 'absolutely clear' to the court, considering the 'procedural safeguards' insulating the new state of affairs from arbitrary reversal and the government's rationale for its changed practice(s), that the activity complained of will not reoccur." *Fikre v. Fed. Bureau of Investigation*, 904 F.3d 1033, 1039 (9th Cir. 2018). While the Government receives more deference under this assessment, the Court still must find that the Government "could not reasonably

be expected" to resume its unlawful conduct. *Friends of the Earth, Inc.*, 528 U.S. 167, 189 (2000).

1. The Defendant has not demonstrated that its change in position is entrenched or permanent.

It is far from "absolutely clear" that Defendant will not continue to unlawfully reject Plaintiff's claims for reimbursement. More than one year ago, this Court granted Plaintiff summary judgment, explicitly holding that "CGM constitutes durable medical equipment." *Olsen I*, ECF No. 39 at 9. Based upon that ruling, the Court remanded the case with "instructions to authorize coverage." *Id.* at 10. In addition to these instructions, the Court also awarded Plaintiff's counsel attorney fees—finding the Defendant's assertions that CGM does not constitute durable medical equipment—was "so obviously wrong as to be frivolous." *Olsen I*, ECF No. 50 at 5. Yet, Defendant has since denied at least three of Plaintiff's claims on the same or similar grounds this Court previously held unlawful, one of which was denied as recently as January of 2022. Although each of these claims has since been paid without judicial intervention—which is to some extent a voluntary change in position—the Court is not assured the pattern of reimbursement denials will not continue.

While Defendant acknowledges these claims were erroneously denied, even describing these denials as "admittedly unacceptable," it attributes each denial to errors in the claims processing, or coding, system. It does not however, offer any

explanation for the unfavorable ALJ or redetermination decisions once the initial denials were challenged. Even granting the Government the deference owed to it, the Court is not confident the complained-of activity will not reoccur.

2. The new final rule does not moot Plaintiff's request for injunctive relief.

In December 2021, the Secretary issued a "final rule" that "makes changes related to: The Durable Medical Equipment." 86 Fed. Reg. 73860 (Dec. 28, 2021) (to be codified a 42 C.F.R. pt. 414). According to Defendant, this rule "supersedes CMS 1682-R, with respect to CGM systems and classifies such systems, including so-called 'non-therapeutic' or 'adjunctive' CGMs, as DME." ECF No. 18 at 4–5. This final rule, which applies to claims dated February 28, 2022 and forward, indicates that "[c]laims submitted for CGM sensors and transmitters used with insulin pumps are being denied inappropriately based on CMS–1682–R even though this Ruling only addressed the classification of CGM receivers as DME and did not address coverage of CGM sensors and transmitters used with insulin pumps." 86 Fed. Reg. at 73898.

This rule, Defendant argues, requires the Secretary to cover claims for CGM sensors and transmitters used with insulin pumps, if submitted after February 28, 2022. ECF No. 18 at 7. Defendant's argument is essentially that the Secretary cannot possibly continue to reject claims for CMS coverage because this new rule prevents it from doing so. *See* ECF No. 18 at 8 ("This new rule effectively ensures

that future CGM claims submitted by Plaintiff and other similarly-situated Medicare claimants will not be denied on the grounds that a CGM is not DME.").

But so did this Court's prior order, which the Secretary routinely defied, issuing unfavorable decisions on Plaintiff's reimbursement claims. Moreover, there is some dispute over whether this new rule makes Plaintiff's claims as bullet-proof as Defendant suggests, but the Court need not assess the effect of this rule, if any, on Plaintiff's future reimbursement claims. Even if this rule directly covers the types of claims submitted by Plaintiff, the Court has significant concerns that Defendant will disregard the rule. For the better part of one year, Defendant failed to comply with this Court's directions to cover Plaintiff's claims, despite a finding that its position was taken in bad faith. The Court thus has little confidence that Defendant will not similarly defy its own dictates. Accordingly, the Government has failed to meet its heavy burden of persuading the Court that its voluntary change in stance moots this action.[4]

B. Plaintiff is not entitled to a preliminary injunction

Having found that Plaintiff's claim is not moot, the Court proceeds to analyze the merits of the requested preliminary injunction. Because the Court finds that

[4] The Court's assessment of mootness is limited to Plaintiff's specific claim for injunctive relief, the Court expresses no judgment on whether the other claims asserted in Plaintiff's Complaint are moot.

Plaintiff cannot show irreparable harm, a prerequisite to injunctive relief, the Court does not analyze the remaining factors.[5]

1. Irreparable harm

"At a minimum, a plaintiff seeking preliminary injunctive relief must demonstrate that it will be exposed to irreparable harm." *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988). Such harm must be "*likely*, not just possible." *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). To establish this factor, "[a] plaintiff must do more than merely allege imminent harm sufficient to establish standing; a plaintiff must *demonstrate* immediate threatened injury as a prerequisite to preliminary injunctive relief." *Caribbean Marine Servs. Co.*, 844 F.2d at 674.

On this front, Plaintiff submits that "absent Medicare coverage, a very large portion of the Medicare beneficiaries (including [Plaintiff]) would simply not be able to afford a CGM and, therefore, would suffer the irreparable harms associated with not having a CGM (e.g., death, blindness, loss of limbs, cognitive decline)." But these harms, while undeniably serious, are not immediately threatened. On this point, the Court notes that each of Plaintiff's reimbursement claims have ultimately been paid, which militates against a finding of immediate threatened injury. Plaintiff

[5] For the same reason, the Court does not reach Defendant's argument that 42 U.S.C. § 405(h) bars the injunctive relief Plaintiff seeks.

does not allege, nor does the record indicate, that at any point Plaintiff has gone without CGM supplies or been forced to pay for them out of pocket. Nor has Plaintiff shown that the delay in reimbursement has impeded or will impede his ability to receive the CGM supplies in a timely manner. Of course, Plaintiff may renew his motion if these circumstances change.

Similarly, Plaintiff has failed to establish irreparable harm to other non-party claimants. Plaintiff's request for injunctive relief seeks a ruling that affects not only his future CGM claims, but also those of all other persons submitting such claims. These unidentified persons are not parties to this action and there is no evidence before the Court suggesting they will suffer the same harm alleged by Plaintiff. "In the absence of medical evidence specific to their need for CGMs," and the absence of medical evidence suggesting that each person submitting a CGM claim will suffer similar harm if not covered, the Court cannot determine that all persons submitting such claims are threated with immediate, irreparable harm. *Lewis v. Becerra*, 2022 WL 123909, at *9 (D.D.C. Jan. 13, 2022). The Court therefore denies Plaintiff's request for a preliminary injunction on this prong alone.

Briefly, though, the Court again notes that Defendant has denied at least three of Plaintiff's claims for reimbursement in direct violation of this Court's previous order directing Defendant to cover such claims. This level of disregard is shocking to the Court, and Defendant shall be on notice that should it deny another of

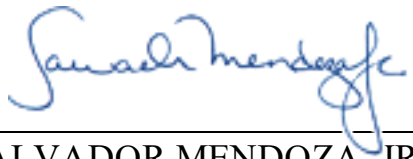
Plaintiff's claims on grounds previously held unlawful, the Court will take all enforcement action within its sound discretion.

Accordingly, **IT IS HEREBY ORDERED**:

1. Plaintiff's Motion for Preliminary Injunction, **ECF No. 6**, is **DENIED**.

IT IS SO ORDERED. The Clerk's Office is directed to enter this Order and provide copies to all counsel.

DATED this 31st day of March 2022.



SALVADOR MENDOZA, JR.
United States District Judge